510(k) Summary

DEC 6 2012

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

A. Submitter's Information

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Date of Preparation:	2 May 2012

B. Device Name

Trade Name:	Fresenius 2008T Hemodialysis Machine with bibag System
Common Name:	Hemodialysis Delivery System
Classification Name:	High Permeability Hemodialysis System
Classification Number:	Class II per § 876.5860
Product Code/Classification Panel:	78KDI/Gastroenterology/Urology Panel

C. Legally Marketed Predicate Device (unmodified device)

Fresenius 2008T Hemodialysis Machine with bibag System (K120017).

D. Device Description

The Fresenius 2008T Hemodialysis Machine with bibag System is indicated for use in bicarbonate hemodialysis for acute and chronic renal failure.

The 2008T Hemodialysis Machine with bibag System allows operators the option to prepare a saturated sodium bicarbonate solution online through automated mixing of dialysis grade water and dry sodium bicarbonate powder within the bibag source disposable. The bibag System comprises: (1) the sodium bicarbonate concentrate generator (known as the bibag module); (2) the bag of dry sodium bicarbonate concentrate. A specialized bibag connector with a door is used to connect the single-use bibag disposable (650g/900g) filled with USP grade dry sodium bicarbonate powder to the bibag connector. The 2008T Hemodialysis Machine draws dialysis grade water into the bibag to produce a saturated solution of sodium bicarbonate online. This online generation of sodium bicarbonate can only be performed using a specially modified Fresenius 2008T Hemodialysis Machine with bibag System and can only be used with 45x (1:44) dilution. The bibag cannot be used with non-Fresenius hemodialysis machines capable of using cartridge type dry sodium bicarbonate because of the unique connection between the bibag disposable, the bibag connector, and the hemodialysis machine.

Modifications to the previously cleared 2008T Hemodialysis Machine with bibag System include:

- **Active Pressure Regulation Feature:** Increases the maximum acid/bicarbonate concentrate inlet pressure specification from 2 psi to 10 psi. Provides an integrated process for regulating concentrate supply (inlet) pressures from central delivery systems.
- **Active Venting Feature:** Replaces the existing venting process requiring dialysate flow bypass.
- **In-line Particulate Filter:** Addition of an inline particulate filter between the bibag concentrate outlet and bicarbonate pump to eliminate the possibility of particulates from the disposable bag from entering the hydraulics.
- **Mute Once Feature:** Users may elect to mute all conductivity and temperature audible alarms for up to 6 minutes (maximum) to allow a newly installed bibag disposable to reach operating temperature and conductivity.
- **Acid Clean/Heat disinfection button:** Allows users to initiate the acid/heat disinfect process with a single screen selection.

This submission also includes a description of software modifications to implement user interface changes. Modifications include: Heparin/SVS status, Dialysate On/Off button, Configurator, SVS Option and are intended to address user preferences and to provide additional user convenience. These changes were also described in K120505 (submitted 17 February 2012; cleared 6 March 2012).

Additionally, this submission includes minor software maintenance changes made to the 2008T Hemodialysis Machine with bibag System since the last clearance (K120017).

Treatment modalities for the modified Fresenius 2008T Hemodialysis Machine with bibag System remain identical to those for the unmodified device (K120017):

> The 2008T Hemodialysis Machine with bibag System is a high permeability hemodialysis system used for the treatment of patients with acute or chronic kidney failure, fluid overload or toxemic conditions. Therapies include hemodialysis, hemofiltration and hemoconcentration. The 2008T will accommodate the use of both low flux and high flux dialyzers.

E. Indications for Use

The modified Fresenius 2008T Hemodialysis Machine with bibag System has the same indications for use as the unmodified device. The Fresenius Medical Care bibag system is used with Fresenius Medical Care three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag System is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

F. Technological Characteristics

There are no changes in the technological characteristics of the previously cleared Fresenius 2008T Hemodialysis Machine with bibag System (K120017). The Fresenius 2008T Hemodialysis Machine with bibag System incorporates changes (hardware, software, labeling) related to performance (active pressure regulation, active venting, particulate filter) and features to facilitate user convenience (Mute Once, Acid/Heat Disinfection button, Heparin/SVS status, Dialysate On/Off button, Configurator, SVS Option).

The modified and the unmodified devices have identical indications for use and are intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The modified device has the same operating principle, fundamental scientific technology, and is comparable in key safety and effectiveness and quality assurance features.

All water requirements, module options, functional options, performance limits, control parameters, compatible bloodlines, and language options remain unchanged from the predicate device.

The following technical specifications of the modified device remain the same as the unmodified device:

- Safety system
- System performance
- Environmental Requirements
- User Interface (except for described modifications)
- Hardware and therapy settings
- Accessories
- Environmental Design
- Alarms (except for additional fault condition alarms)
- Accuracy and Controls
- Protection against Mechanical Hazard
- Protection against Electrical Hazard
- Protection against excessive temperature or other hazards
- Transportation and Storage conditions
- Manufacturing Location and manufacturing processes (assembly, fabrication, testing, shipping, installation and service).

A risk analysis (per ISO 14971) has been completed and potential hazards associated with the modifications are identified and mitigated. Mitigations are verified wherever applicable. All potential risks were deemed acceptable after mitigation. Performance and safety tests were conducted to ensure the safety and effectiveness of the device after the proposed modifications.

G. Performance Data

The performance of the modified device described in this submission was evaluated according to existing FMCNA procedures, protocols, declared performance standards and guidelines of the quality system regulation (21 CFR 820). Design verification and validation tests were conducted to ensure that the modifications did not affect the essential performance of the device and the device functions as intended.

The following tests were conducted for the modified device:

6. **System and Software Verification and Validation Testing**
   - Functional Verification and Software Validation
     - Software Verification (Functional Tests)
     - Regression
     - Safety Systems Verification
     - Simulated Dialysis Treatment
     - Production Test Procedure
     - Unstructured and Static Code Verification
   - System Performance
   - Heat Disinfection Testing
   - Chemical Testing

7. **System Safety**
   - Equipment Safety
   - Electromagnetic Compatibility

8. **Reliability**
   - High Accelerated Life Testing
   - Mechanical Life Testing
   - Elevated Temperature Testing

9. **Biocompatibility**

10. **Summative Usability**

H. Conclusion

Test results demonstrated that the modified 2008T Hemodialysis Machine with bibag System functions as intended and met pre-determined acceptance criteria. Results of system/software verification/validation testing, safety testing, reliability testing, biocompatibility tests, summative usability study and risk analysis indicate that the modified Fresenius 2008T Hemodialysis Machine with bibag System is substantially equivalent to the named predicate device and remains safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 6, 2012

Fresenius Medical Care, North America
% Ms. Denise Oppermann
Senior Director
920 Winter Street
WALTHAM MA 01854

Re: K121341
Trade/Device Name: 2008T Hemodialysis Machine with bibag™ System
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, KPO
Dated: November 21, 2012
Received: November 23, 2012

Dear Ms. Oppermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

Acting Director for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121341

Device Name:

2008T Hemodialysis Machine with bibag™ System

Indications for Use:

The Fresenius bibag system is used with Fresenius three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

☒ Prescription Use (Per 21 CFR 801 Subpart D)

AND/OR

☐ Over-the-Counter Use (21 CFR 801 Subpart C)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121341